

REMARKS

The present application was filed on March 27, 2001 (claiming priority from United States Provisional Application Number 60/245,396, filed November 2, 2000) with claims 1-43. Claims 7-21, 28-32 and 39-43 have been withdrawn from consideration in response to a restriction requirement and claims 4, 25 and 36 have been withdrawn from consideration in response to a species election. Therefore, claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 are presented herein for examination on the merits. Applicant acknowledges that while claims 4, 7-21, 25, 28-32, 36 and 39-43 have been withdrawn from consideration, as highlighted above, these claims are still pending in the present application. Claims 1, 5, 6, 22, 26, 27, 33, 37 and 38 are proposed to be amended herein. No new matter has been introduced. Support for the amendments made to claims 1, 5, 6, 22, 26, 27, 33, 37 and 38 can be found, for example, on page 11, lines 18-19 and 22-24, pages 4-5, lines 26-1, page 5, lines 26-27, page 8, lines 6-7, as well as on page 9, lines 4-5, of the specification.

In the outstanding Office Action, the Examiner rejected claim 1, and claims dependent therefrom, under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner also rejected claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38 under 35 U.S.C. §101 because the claimed invention allegedly lacks patentable utility. The Examiner rejected claims 1, 3, 6, 22, 24, 27, 33, 35 and 38 under 35 U.S.C. §102(b) as allegedly anticipated by J. L. Cornette et al., *Hydrophobicity Scales and Computational Techniques for Detecting Amphipathic Structures in Proteins*, J. MOL. BIOL. 195, pgs. 659-685 (1987) (hereinafter "Cornette"). The Examiner further rejected claims 1-3, 6, 22, 24, 27, 33, 35 and 38 under 35 U.S.C. §102(b) as allegedly anticipated by Eisenberg et al. Faraday Symposia of the Chemical Society, 1982, 17, 109-120 (hereinafter "Eisenberg").

The present invention has been described in Applicant's prior response, incorporated by reference herein.

The comments of the Examiner in forming the rejections are acknowledged and have been carefully considered.

FORMAL REJECTIONS

As mentioned above, the Examiner rejected claim 1, and claims dependent therefrom, under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Examiner stated, with regard to independent claim 1, that the claim is “indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble.” See, Office Action, beginning on page 2, paragraph 2A. Specifically, the Examiner stated that the “claim does not set forth the conditions when determining/shifting of hydrophobicity distribution results in ‘spatially profiling proteins.’” See *Id.*

Applicant has amended independent claim 1, thereby overcoming the Examiner’s rejections. Support for the amendment can be found, for example, on page 11, lines 18-19 and 22-24, pages 4-5, lines 26-1, as well as page 5, lines 26-27, of the specification. Applicant submits that the included limitation of comparing the shifted hydrophobicity distribution of the protein to globular protein results properly sets forth the conditions when the determining/shifting of hydrophobicity distribution results in spatially profiling a protein to determine if the protein is a globular protein.

Furthermore, Applicant points to page 11, lines 18-24, of the specification wherein it is stated that,

[i]n step 180, results from examining the current protein can be compared with results determined previously.... If the protein being examined has profiles that are of a shape similar to the general profile, then the current protein is assumed to belong to the class of protein defined by the set of proteins.

On page 5, lines 25-27, of the specification, it is further stated that, “Globular proteins tend to exhibit a certain range of these distance ratios. If a protein or decoy has a hydrophobicity ratio that is not within the range, then the protein or decoy is likely not a globular protein.”

Given the above remarks, Applicant respectfully asserts that claim 1 does “set forth the conditions when determining/shifting of hydrophobicity distribution results in spatially profiling a protein to determine if the protein is a globular protein. Consequently, it is Applicant’s position that one of ordinary skill in the art would be able to ascertain the metes and bounds of

the present claims from the teachings of the specification. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Also, beginning on page 3, paragraph B, of the outstanding Office Action, the Examiner states that, with regard to the previously amended claim 1, "it is not clear what aspects of a three-dimensional structure are intended to be described." Applicant has amended independent claim 1, removing the language in question, thereby overcoming the Examiner's rejection.

As further highlighted above, the Examiner rejected claims 1-3, 6, 22-24, 27, 33-35 and 38 under 35 U.S.C. §101 because the claimed invention allegedly lacks patentable utility. Specifically, the Examiner stated beginning on the bottom of page 4 of the outstanding Office Action that,

the method provides "the capability" of spatially profiling the hydrophobicity distribution of amino acid residues which can further be utilized in analysis of three-dimensional structure; i.e., further research steps are required for the method to have a demonstrated substantial utility.

As Applicant previously pointed out, Applicant has amended independent claims 1, 22, and 33, from which claims 2, 3 and 6, 23, 24 and 27, and 34-35 ultimately depend, respectively, thereby overcoming the Examiner's rejection. Amended independent claim 1 demonstrates substantial utility by disclosing a method for spatially profiling a protein to determine if the protein is a globular protein. On page 4, lines 16-21, of the specification, Applicant illustrates that

[t]he present invention may be used to analyze any protein but is particularly useful for analyzing proteins that form in an aqueous environment, such as globular proteins.... globular proteins exhibit certain characteristics that can be determined by the present invention. These characteristics can be used to analyze a protein or decoy (a man-made protein) to see if it is a globular protein. (Emphasis added).

Moreover, on page 18, lines 16-19, Applicant states that

5 [i]n the case of globular proteins, heretofore unseen characteristics and similarities between relatively diverse proteins have been shown. Moreover, the present invention allows decoy and unrelated proteins to easily be excluded from a group of already examined and similar proteins.

10 The substantial utility standard is met when a “specific benefit exists in currently available form.” *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966). Here, as illustrated above, the specific benefit is the spatial profiling of a protein to determine if the protein is a globular protein. As a result, Applicant also submits that no further research steps are required for the method to have a demonstrated substantial utility. Even in the alternative, however, the Federal Circuit has held that usefulness “necessarily includes the expectation of further research and development.” *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

15 Given the above remarks, Applicant respectfully submits that claims 1-3, 6, 22-24, 27, 33-35 and 38 fully comport with the requirements of 35 U.S.C. §101 and as such, Applicant respectfully requests reconsideration and withdrawal of the rejections.

PRIOR ART REJECTIONS

20 As mentioned above, the Examiner reiterated the previous rejection of claims 1, 3, 6, 22, 24, 27, 33, 35 and 38 under 35 U.S.C. §102(b) as allegedly unpatentable over Cornette. On page 5, 5th paragraph, of the Office Action dated October 7, 2005, the Examiner stated that,

25 Cornette teaches calculation of hydrophobic moment for each residue (cf. claim 6) - i.e., determining ‘hydrophobicity distribution’ - and plotting them on a graph. See p. 660, right column through p. 661, left column, and Fig. 2.... For comparative purposes, to compare different approaches, the hydrophobicity values are normalized (cf. claim 3) to have a value of 1000 at the frequency angle of 100° (i.e., ‘hydrophobicity distribution’ is ‘shifted’).

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As noted above, Applicant has amended independent claims 1, 22, and 33, from which claims 2, 3 and 6, 23, 24 and 27, and 34-35 ultimately depend, respectively, thereby overcoming

the Examiner's rejection. Applicant argues that Cornette does not teach or suggest the step of comparing the shifted hydrophobicity distribution of the protein to globular protein results to determine if the protein is a globular protein. Cornette teaches a means for "associating amphipathic secondary structure in a protein molecule with the sequence of hydrophobicity values of its residues." Page 660, Introduction.

In contrast, Applicant submits that the presently claimed invention is a method to determine if an example protein belongs to the class of globular proteins. See, for example, page 2, lines 21-22, of the specification.

Therefore, Applicant submits that because Cornette does not teach or suggest anything relating to globular proteins, let alone a method used to determine whether a given protein is a globular protein, claims 1, 3, 6, 22, 24, 27, 33, 35 and 38 of the present invention are not anticipated by Cornette. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As such, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 3, 6, 22, 24, 27, 33, 35 and 38 over Cornette.

As mentioned above, the Examiner also rejected claims 1-3, 6, 22, 24, 27, 33, 35 and 38 under 35 U.S.C. §102(b) as allegedly anticipated by Eisenberg. Beginning on page 6, 5th paragraph, of the outstanding Office Action, the Examiner stated that,

Eisenberg "normalized" hydrophobicity by averaging the normalized hydrophobicities for each residue over five scales, and by multiplying the result by standard deviation and adding it. Thus, the Eisenberg reference is viewed as reading on the instantly claimed method comprising steps of shifting hydrophobicity distribution based on a difference between values in the hydrophobicity distribution and an average hydrophobicity value.

As noted above, Applicant has amended independent claims 1, 22, and 33, from which claims 2, 3 and 6, 23, 24 and 27, and 34-35 ultimately depend, respectively, thereby overcoming

the Examiner's rejection. Applicant argues that Eisenberg does not teach or suggest the step of comparing the shifted hydrophobicity distribution of the protein to globular protein results to determine if the protein is a globular protein. Eisenberg examines

5 the hydrophobic dipole moments in the known structures of
 nine globular proteins and find[s] that the moments of
 neighbouring segments tend to point towards each other.
 (Emphasis added). Page 109, paragraph 2.

10 Therefore, Applicant submits that the step of "comparing the shifted hydrophobicity
 distribution of the protein to globular protein results to determine if the protein is a globular
 protein" as stated in amended independent claim 1 of the present invention is not anticipated by
 Eisenberg because the Eisenberg reference simply examines known structures, whereas the
 present invention determines "if an example protein belongs to a particular class of protein, such
 as globular proteins." Page, 2, lines 21-22, of the specification. "A claim is anticipated only if
 15 each and every element as set forth in the claim is found, either expressly or inherently
 described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814
 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

 As such, Applicant respectfully requests reconsideration and withdrawal of the rejection
 of claims 1, 3, 6, 22, 24, 27, 33, 35 and 38 over Eisenberg.

20 Also, beginning on page 8, line 4, of the specification, Applicant explains that the spatial
 distribution of hydrophobicity of a globular protein (as per, e.g., independent claim 1) is
 calculated from the inside of a globular protein to the outside over the entire area of the
 representative surface. Neither Cornette nor Eisenberg teach or suggest such a means of
 calculating the spatial distribution of hydrophobicity of a globular protein.

25 In view of the foregoing, the invention cannot be said to be taught or suggested by
 Cornette or Eisenberg. Accordingly, Applicant submits that all claims presented here for
 examination, i.e., claims 1-3, 5, 6, 22-24, 26, 27, 33-35, 37 and 38, are in condition for allowance
 and such favorable action is earnestly solicited.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.

The Examiner's attention to this matter is appreciated.

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Respectfully submitted,



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